

REMARKS

Favorable reconsideration and allowance of this application are requested.

I. Claim Amendments

By way of the amendment instructions above, independent claim 1 has been revised so as to emphasize that at least one traction-resistant fibre is wound around the upper, lower **and** lateral surfaces of a nucleus of flexible material in the form of a flattened body so as to establish substantially **radially oriented** windings on the **lower and upper surfaces** thereof. Support for such language may be found throughout the originally filed specification, for example, at page 3, lines 13-33.

Many of the originally filed dependent claims have been revised so as to employ language consistent with that now employed in the amended version of claim 1.

Claims 10-15 are new and depend from the amended version of claim 1. In this regard, relative shapes of the lower and upper surfaces of the flattened body are defined by new claims 10-11 as supported at page 2, lines 22-23. The length of the traction fibres is specified in new claims 12-13 in terms of the circumference of the nucleus as supported at page 4, line 35 through page 5, line 7. New claims 14-15 specify that several traction resistant fibres may be employed to establish the radially oriented windings and to be wound around laterally around the lateral surface of the flattened body as supported at page 5, lines 2-7.

New independent claim 16 has been presented for consideration and is substantively similar to the revised version of claim 1 with a principal exception being that the former recites the relative length of the traction-resistant fibre. (See page 5, lines 1-3) Claim 17 is dependent from independent claim 16 and recites the presence and relative length of the lateral traction-resistant fibre. (See page 5, lines 5-7) Claim

18 recites a preferred tensile strength and modulus of the traction-resistant fibres. (See page 5, line 8-11)

Therefore claims 1-18 are presently pending in this application for which favorable reconsideration and allowance are solicited.

II. Response to Art-Based Rejections

The only issue to be resolved in this application is the Examiner's rejection of prior claims 1-9 as allegedly anticipated (35 USC §102(e)) by Trieu (USP 6,733,531). In this regard, the Examiner asserts that Trieu '531 discloses an intervertebral disk comprising a flexible nucleus around which at least substantially radially oriented windings of a traction-resistant fibre have been applied. As will become evident from the following discussion, however, Trieu '531 does not render the presently claimed invention unpatentable.

Trieu '531 discloses an implant system comprising an elastic spinal implant having a longitudinal axis, an anchoring component and a peripheral supporting band disposed circumferentially about the implant (see page 17, claim 3, lines 1 to 12). Trieu '531 further discloses a method of securing the band in place to prevent slipping or sliding, and provide additional reinforcing by using straps extending over upper and lower surfaces. The ends of the straps are attached to the peripheral supporting band and furthermore, more than one strap may be used (page 12, lines 63 to 67, and page 13 lines 1 to 22).

Applicant specifically wishes to direct the Examiner's attention to the fact that Trieu '531 uses a band around a nucleus lateral surface -- meaning or course that a strip of material with a characteristic width higher than its thickness (See Figures 18 and 19 of Trieu '531) is used to avert eventual nucleus deformations. In contrast with Trieu's chosen configuration, the present invention uses the windings of a fibre to contain

nucleus deformations (See Figure 1 of the present application). This novel feature is clearly emphasized by Claim 1 of the present application, wherein it is stated:

"... at least substantially radially oriented windings of a traction-resistant fibre have ..."

By visually comparing Figures 18 and 19 of Trieu '531 with Figure 1 of the present application, one skilled in the art immediately notices the substantial difference in shape, positioning and size between the two different articles used to help restricting nucleus deformations. The supporting band and/or straps used by Trieu '531 cannot be possibly formed of a **single** traction-resistant fibre, wound around the upper, lower **and** lateral surfaces of the nucleus. Therefore, the clear structural difference between bands/straps of Trieu '531 on the one hand and the claimed fibres of the present invention on the other hand preclude the former from being an anticipatory reference of the latter under 35 USC §102(e).

Withdrawal of the rejection advanced under 35 USC §102(e) is therefore in order.

In order to advance prosecution of this application, applicant also notes that the presently claimed invention is unequivocally "unobvious" (35 USC §103(a)) over Trieu '531. Specifically, applicant notes that there are clearly unobvious structural and functional distinctions as between the intervertebral discs of Trieu '531 and the present invention.

In this regard, applicant notes the fact that an intervertebral prosthesis is subjected to a tremendous amount of stress in different forms such as compression, shear and torque. The distribution of stress inside a rubber or gel-like material will result in local load variations, and subsequently in shape variations throughout the entire volume of the nucleus. Thus, pressing down the nucleus at one place causes a stress redistribution resulting in protrusions at another location.

The occurrence of such protrusions is avoided according to the present invention by applying a traction-resistant fibre around the nucleus. The windings only permit

some shape variations in the longitudinal directions of the vertebral column, but substantially do not permit shape variations in a direction perpendicular thereto (see the present application at page 3 lines 1 to 12). In contrast, the lateral band and straps of the Trieu '531 intervertebral disk cover only a relatively small area of the total nucleus surface whereas in the present invention, the nucleus is enveloped by a traction-resistant fibre.

Accordingly, a much more effective restraining effect is obtained by winding a fibre along substantially radial directions, hence helping to maintain the shape of the nucleus. As a result, the eventual occurrence of undesired nucleus protuberances is virtually eliminated in the present invention, whereas in the Trieu '531 disk, there is the risk of such events occurring at the locations which are not covered by the band and/or straps.

A further very important feature, distinguishing the present invention from Trieu '531 is also related to the effective restraining effect provided by the traction-resistant fibres. In this regard, because of the improved stabilization effect on the nucleus, no further additional anchoring devices are needed to fixate the artificial intervertebral disk between vertebrae in accordance with the present invention. In contrast, Trieu '531 suggests using additional devices to further reinforce and fixate the flexible spinal implant. Specifically Trieu '531 suggests anchoring devices in different shapes and forms (Figures 1 to 8 of Trieu '531) as well as different methods of fastening the spinal implants between adjacent vertebrae

In direct contrast to such teachings of Trieu '531, the present invention makes use of patterns created by winding the traction-resistant fibre(s) around the flexible nucleus (see the original specification at page 5 lines 25 to 35, and page 6 lines 1-2). Such patterns can be adjusted by suitably choosing the thickness of the fibre (see the original specification at page 5 lines 20-23) or by a suitable winding process (see the original specification at page 6 lines 1-2). The pattern or protuberances induced by the

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wound fibre(s) are in and of themselves enough to provide a secure fixation of the spinal implant between the vertebral bodies.

III. Conclusions

Every effort has been made to advance prosecution of this application to allowance. Therefore, in view of the amendments and remarks above, applicant suggests that all claims are in condition for allowance and Official Notice of the same is solicited.

Should any small matters remain outstanding, the Examiner is encouraged to telephone the Applicants' undersigned attorney so that the same may be resolved without the need for an additional written action and reply.

An early and favorable reply on the merits is awaited.

Respectfully submitted,

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